



Transcatheter Aortic Valve Replacement (TAVR) Outcomes Reporting

**Kick-off Webinar
December 8, 2022**

Agenda

- Introductions
- Background
- Regulations (effective January 1, 2023)
- Data Release Consent Form
- Outreach
- Next steps for hospitals
- Timeline
- Q and A

Background

2021 Revisions to California Health and Safety Code

- HCAI shall publish at least one risk-adjusted outcome report for CABG, TAVR, or any type of interventional cardiovascular procedure for procedures performed in the state. For any type of interventional cardiovascular procedure other than CABG or TAVR, the department shall only select from interventional cardiovascular procedures recommended by the CAP, not to exceed one additional interventional cardiovascular procedure every three years
- Upon recommendation of the CAP, HCAI may add any clinical data elements included in the STS database or other relevant databases to be collected from hospitals.
- If, at the time HCAI decides to report on a procedure, the CAP does not have members with expertise in that procedure, HCAI shall seek to appoint two new members with expertise in that procedure from a list submitted by the CAACC.

CABG – Coronary artery bypass graft surgery

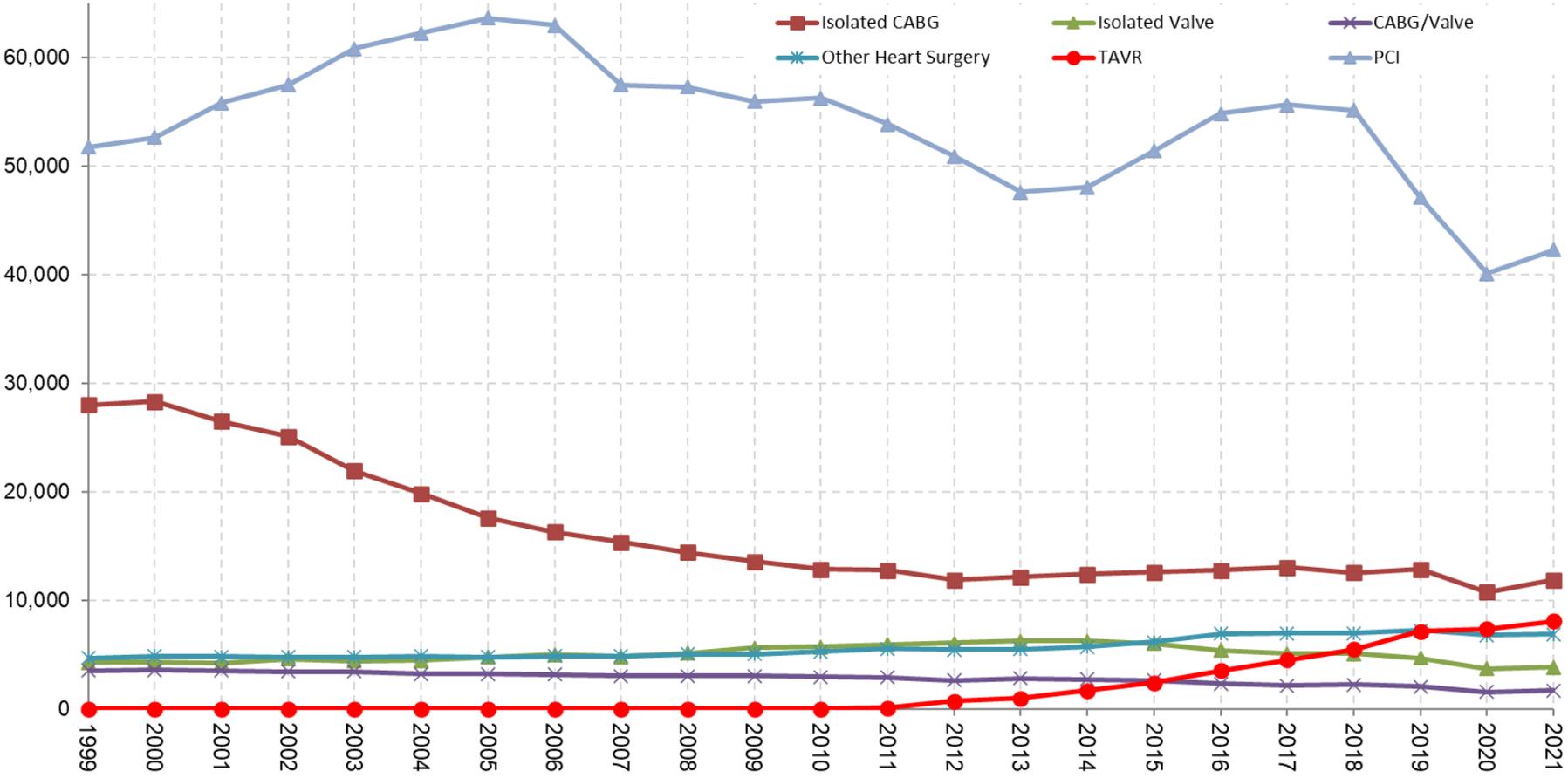
TAVR – Transcatheter aortic valve replacement

CAP – Clinical Advisory Panel

STS - Society of Thoracic Surgeons

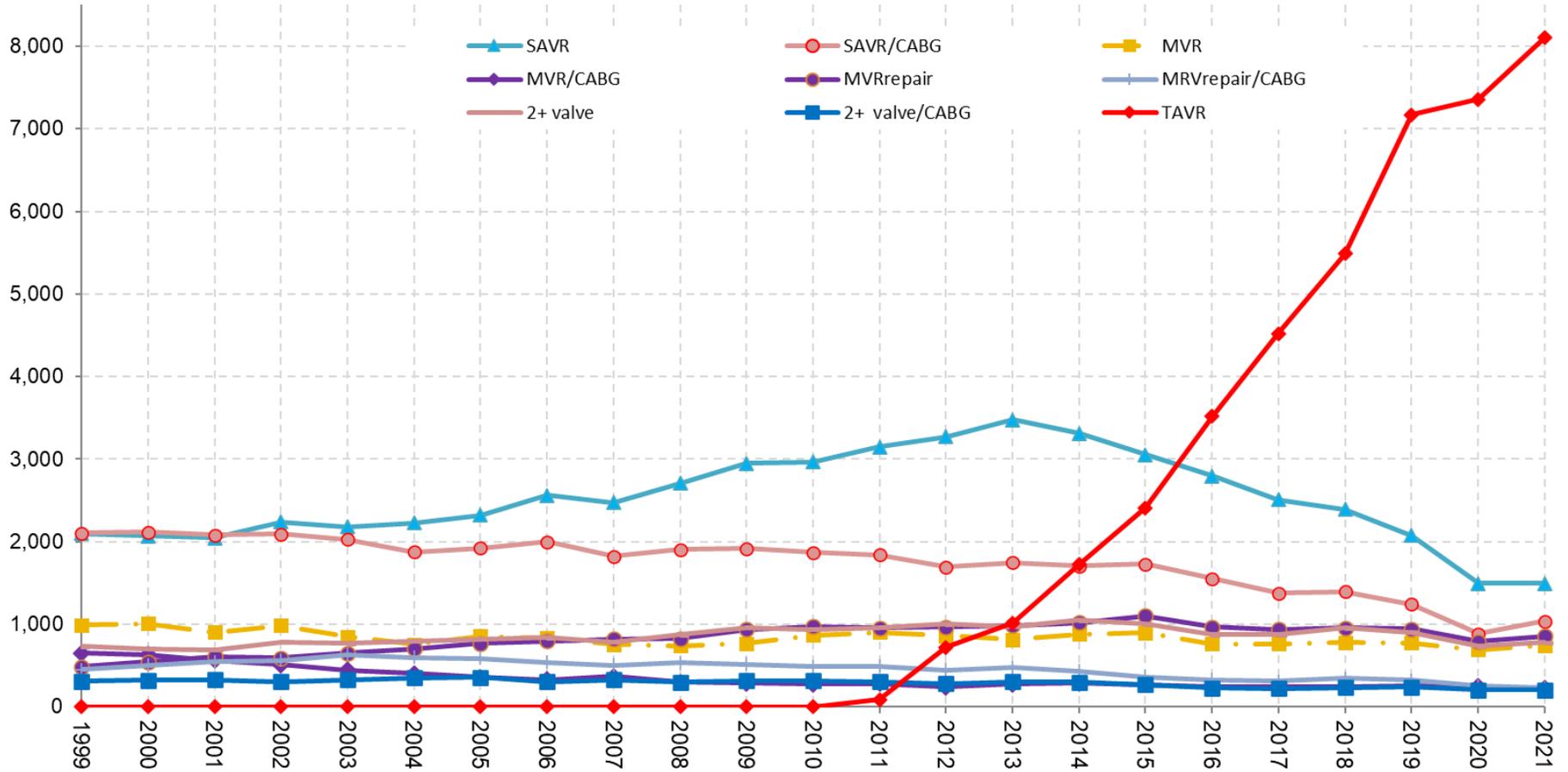
CAACC - California Chapter of the American College of Cardiology

Volume of Cardiovascular Procedures and Interventions 1999-2021



Source: HCAI PDD, AS, ED

Volume of Valve Procedures and Interventions 1999-2021



Source: HCAI PDD, AS, ED

Previous Webinars

- History of CABG and PCI reporting at HCAI
- Recent Legislation
- Role and additions to CAP
- Center for Medicare and Medicaid Services requirements related to TAVR
- STS/ACC TVT Registry™ (TVT Registry)
- Proposed regulations
- Webinar presentations and Q&As available at <https://hcai.ca.gov/data-and-reports/transcatheter-aortic-valve-replacement-outcomes-reporting/>

November 4, 2021 CAP Meeting – CAP Recommendations

- HCAI proceed with TAVR public reporting at the hospital level.
- Hospital reporting of TAVR data should be mandatory (CAP discussed the pros and cons of mandatory versus voluntary hospital reporting).
- Add two new two interventional cardiologists who have expertise in interventional approaches to structural heart disease and seek nominations from both the California ACC and the California STS.

April 13, 2022 CAP Meeting – Highlights

- Dr. Nakamura and Dr. Rassi sworn in as new CAP members
- CAP approved that data from the TVT Registry be used as the major source for the HCAI report.
- CAP voted that that all hospitals that perform TAVR procedures in the State of California not only participate in the TVT Registry, but also submit that data required by the state for potential analysis and public reporting, with no low volume exception.

November 1, 2022 CAP Meeting – Highlights

- CAP recommended changing the name of HCAI's program from the California CABG Outcomes Reporting Program to the California Cardiovascular Outcomes Reporting Program retaining the acronym CCORP.

Clinical Advisory Panel (CAP)

The current CAP includes 11 members nominated by the following:

- California Chapter of the American College of Cardiology
- California Medical Association
- Consumer Organizations

Panel Member	Role	Nominated by
Ralph G. Brindis, M.D., MPH (Chair)	Interv. Cardiologist (Ret)	California ACC
Cheryl Damberg, Ph.D.	Healthcare Researcher	Consumers Union
Gordon L. Fung, M.D., MPH, Ph.D.	General Cardiologist	California Medical Association
Hon S. Lee, M.D.	CV Surgeon	California Medical Association
James MacMillan, M.D.	CV Surgeon	California Medical Association
Rita F. Redberg, M.D.	General Cardiologist	Consumers Union
Richard J. Shemin, M.D.	CV Surgeon	California ACC
J. Nilas Young, M.D.	CV Surgeon	California ACC
Maribeth Shannon, M.S.	Consumer Representative	Consumers Union
Andrew Rassi, M.D.	Interv. Cardiologist	California ACC
Mamoo Nakamura, M.D., Ph.D.	Interv. Cardiologist	California ACC

TVT Registry

STS/ACC TVT Registry™



The Society of Thoracic Surgeons



AMERICAN COLLEGE of CARDIOLOGY

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Data Collection

Training and Education

Leadership

Research

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Public Reporting

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Participant Directory

Privacy Policy

STS/ACC TVT Registry

About the Registry

Created by a collaboration between the Society for Thoracic Surgeons (STS) and the American College of Cardiology (ACC), the **STS/ACC TVT Registry™** monitors patient safety and real-world outcomes related to transcatheter valve replacement and repair procedures – emerging treatments for valve disease patients. Employing state-of-the-art heart valve technology, transcatheter heart valve procedures provide new treatment options for patients who are not eligible for conventional heart valve replacement or repair surgery.

The TVT Registry has been approved by the Centers for Medicare and Medicaid Services (CMS) to meet the registry requirements outlined in the national coverage determination for [transcatheter aortic valve replacement \(TAVR\)](#) and [transcatheter edge-to-edge repair \(TEER\)](#).

An Invaluable Data Source

Analysis of TVT Registry data allows the cardiovascular profession and medical community to understand how transcatheter heart valve procedures are being deployed throughout the U.S., and what impact they will have on patient outcomes as they become more prevalent. Data from the registry also assists the medical device industry and the FDA in surveillance of the quality, safety and efficacy of new medical devices.

Employing Key Experience

The TVT Registry was developed through a partnership between the STS and ACC. The TVT Registry is backed by a breadth of expertise and resources, including the Federal Drug Administration (FDA), Centers for Medicare & Medicaid Services (CMS) and with input from the Society for Cardiovascular Angiography and Intervention (SCAI) and the American Association for Thoracic Surgery (AATS).

Participants

[View a list of current TVT Registry participants](#)

Regulations

§ 97140. Definitions, as Used in this Article.

- (a) "Department" means the Department of Health Care Access and Information (HCAI).
- (b) "TAVR" means transcatheter aortic valve replacement.
- (c) "TAVR hospital" means a California licensed general acute care hospital that performs TAVR.
- (d) "Program" means the Department's TAVR outcomes reporting program.
- (e) "NCDR®" means National Cardiovascular Data Registry.
- (f) "STS/ACC TVT Registry™" means the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry.
- (g) "DRCF" means the Data Release Consent Form and Addendum to the TVT Registry Participation Agreement Between the American College of Cardiology Foundation, the Society of Thoracic Surgeons, and Participant (November 2022) which is hereby incorporated by reference and available on the Department's website.

Regulations

§ 97145. TAVR data.

(a) TAVR hospitals shall:

(1) Participate in and provide timely submission of TAVR data elements from the STS/ACC TVT Registry™ TAVR Version 3.0 Data Collection Form (November 22, 2021), hereby incorporated by reference, to the STS/ACC TVT Registry™.

(2) Confer rights to transfer the TAVR data submitted pursuant to paragraph (1) to the Department by completing and signing the DRCF and submitting it to the American College of Cardiology NCDR® at the email address on the DRCF and sending a copy of the executed form to the Program via email at TAVR@hcai.ca.gov. The DRCF is available for download from HCAI's website and the Department will make a hardcopy available on request.

(b) For hospitals performing TAVR between January 1, 2022 and December 31, 2022 the DRCF shall be completed, signed and submitted by March 1, 2023.

(c) For hospitals that did not perform TAVR in calendar year 2022 but perform TAVR after December 31, 2022, the DRCF shall be completed, signed and submitted by March 1 of the year following the year TAVRs were performed.

(d) This section shall not apply to a hospital where all TAVRs performed are on patients under 18 years of age on the date of the procedure.

Regulations

§ 97150. Compliance.

TAVR hospitals that do not meet the requirements specified in § 97145 (a), (b), and (c) shall be deemed and reported as non-compliant in the annual outcomes report.

§ 97155. Hospital Data Contact.

(a) Each TAVR hospital shall designate a primary data contact person. A hospital shall notify Program of the designation by email at TAVR@hcai.ca.gov within 30 days of the effective date of this regulation or within 30 days of beginning or resuming TAVR procedures. A notification shall include the designated person's name, title, telephone number(s), mailing address, and email address.

(b) A TAVR hospital shall notify Program by email at TAVR@hcai.ca.gov within 30 days after any change in the person designated as the primary TAVR data contact person, or in the title, telephone number(s), mailing address, or email address, of the individual.

Regulations

§ 97160. Audit Procedure.

(a) The Department may conduct periodic audits of a hospital's patient medical records for its TAVR patients. Audits may be performed remotely or at the hospital's location.

(b) The Department shall notify a hospital a minimum of two weeks before the date of an audit. Upon notification that an audit is planned, a hospital shall designate a person to serve as the audit contact person. A hospital shall provide to the Department the contact person's name, title, telephone number, and email address.

(c) A hospital shall retrieve and make available the requested patient medical records for an audit, and if requested by the Department, provide a reasonable space in which the Department may conduct an audit.

(d) Data abstracted during an audit may, at the Department's discretion, replace data HCAI acquires from the STS/ACC TVT Registry™. Replacement data shall be used in calculating risk-adjusted mortality rates for outcomes reports.

Data Release Consent Form (draft)

DATA RELEASE CONSENT FORM AND ADDENDUM TO THE TVT REGISTRY PARTICIPATION AGREEMENT BETWEEN THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION, THE SOCIETY OF THORACIC SURGEONS AND PARTICIPANT

This Data Release Consent Form and Addendum (“Addendum”) to the TVT Registry Participation Agreement (“Participation Agreement”) between the undersigned Hospital Participant (“Hospital Participant”), the undersigned Surgeon (“Surgeon Participant”), the undersigned Cardiologist (“Cardiologist Participant”), the American College of Cardiology Foundation (“ACCF”) and The Society of Thoracic Surgeons (“STS”) is entered into and made effective on the latest date signed below (“Effective Date”). The Hospital Participant, Surgeon Participant, and Cardiologist Participant shall be referred to herein collectively as “Participant.” ACCF and STS shall be referred to herein collectively as “ACCF/STS”. ACCF/STS and Participant shall each be referred to herein as a “Party” and collectively as the “Parties.” All existing terms and conditions of the Participation Agreement shall remain in full force and effect.

For good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties further acknowledge and agree as follows:

Data Release Consent Form (draft)

SAMPLE – DO NOT USE

1. Participant has entered into a Participation Agreement and a Business Associate Contract and Data Use Agreement (“BAC/DUA”) with ACCF/STS to provide certain transcatheter valve therapies patient-level data to ACCF/STS (“TVT Data”) and to receive certain comparative and benchmark reports from ACCF/STS. TVT Data include certain required patient identifiers and such data include Protected Health Information (“PHI”) as defined under the regulations issued pursuant to the Health Insurance Portability and Accountability Act of 1996 (“HIPAA regulations”).
2. Pursuant to Sections 97140-97160 of Title 22 of the California Code of Regulations, as amended, Participant is required to participate in the TVT Registry and confer the right to transfer the TAVR data submitted by the Participant to the California Department of Health Care Access and Information (“HCAI”). To fulfill such requirement, Participant agrees to permit the transmission by ACCF/STS to HCAI of Participant’s data submitted to the TVT Registry, and to further permit the disclosure of Participant’s PHI to CA HCAI.
3. Participant acknowledges that it has been informed that ACCF/STS and HCAI have entered or will enter into an agreement, the purposes of such agreement being to provide to HCAI in a secure manner reports, including Participant’s row-level data and aggregate data, to HCAI.
4. Participant authorizes and directs ACCF/STS to transmit Participant’s TVT Registry data to HCAI for the purposes described in Paragraph 3 above.

Data Release Consent Form (draft)

SAMPLE – DO NOT USE

5. This Addendum shall be effective for the duration of Participant's participation in the TVT Registry unless earlier terminated as permitted herein. This Addendum may be terminated by Participant or ACCF/STS upon written notice to the other Party at any time. Termination of this Addendum shall not constitute a termination of the Participation Agreement, unless otherwise agreed to by Participant or ACCF/STS.

6. As amended by this Addendum, the Participation Agreement is in all respects ratified and confirmed, and the Participation Agreement and this Addendum shall be read, taken, and construed as one and the same instrument. If there is any inconsistency between (a) the Participation Agreement and/or the BAC/DUA and (b) this Addendum, then the terms of the Participation Agreement and/or the BAC/DUA shall control and prevail.

7. This Addendum may be executed in one or more counterparts, each of which shall be deemed an original and all of which taken together shall constitute one and the same instrument.

Data Release Consent Form (draft)

IN WITNESS WHEREOF, each of the Parties hereto has caused this Addendum to be executed as of the ___ day of _____, 20__:

SAMPLE – DO NOT USE

HOSPITAL PARTICIPANT	ACCF/STS
Signature: _____ Name: _____ Title: _____ Date: _____ E-Mail Address: _____ Phone: _____	Signature: _____ Name: _____ Title: _____ Date: _____
SURGEON PARTICIPANT	
Signature: _____ Name: _____ Title: _____ Date: _____ E-mail Address: _____	
CARDIOLOGIST PARTICIPANT	
Signature: _____ Name: _____ Title: _____ Date: _____ E-Mail Address: _____	

TVT Registry Data Collection

- TVT v3 Data Collection Form includes:
 - Full Dataset
 - Basic Dataset (BOS) is highlighted on the form
 - Minimum data required by the TVT Registry
 - Includes everything necessary for executive summary metrics
 - Allows HCAI to perform risk-adjustment for initial outcomes report
 - Appropriate Use Criteria (AUC) also noted on form
 - HCAI encourages hospitals to submit these data elements

TVT v3 Data Collection Form

 Transcatheter Aortic Valve Replacement (TAVR) v3 Data Collection Form		STS/ACC TVT Registry™
A. DEMOGRAPHICS		
Last Name ²⁰⁰⁰ :	First Name ²⁰¹⁰ :	Middle Name ²⁰²⁰ :
Birth Date ²⁰⁵⁰ : mm / dd / yyyy	SSN ²⁰³⁰ : - - □ SSN N/A ²⁰³¹	Patient ID ²⁰⁴⁰ : (auto)
Other ID ²⁰⁴⁵ :	Sex ²⁰⁶⁰ : <input type="radio"/> Male <input type="radio"/> Female	Patient Zip Code ²⁰⁶⁵ : □ Zip Code N/A ²⁰⁶⁶
Race: (check all that apply)	<input type="checkbox"/> White ²⁰⁷⁰ <input type="checkbox"/> Black/African American ²⁰⁷¹ <input type="checkbox"/> American Indian/Alaskan Native ²⁰⁷³ <input type="checkbox"/> Asian ²⁰⁷² → If Yes, <input type="checkbox"/> Asian Indian ²⁰⁸⁰ <input type="checkbox"/> Chinese ²⁰⁸¹ <input type="checkbox"/> Filipino ²⁰⁸² <input type="checkbox"/> Japanese ²⁰⁸³ <input type="checkbox"/> Korean ²⁰⁸⁴ <input type="checkbox"/> Vietnamese ²⁰⁸⁵ <input type="checkbox"/> Other ²⁰⁸⁶ <input type="checkbox"/> Native Hawaiian/Pacific Islander ²⁰⁷⁴ → If Yes, <input type="checkbox"/> Native Hawaiian ²⁰⁹⁰ <input type="checkbox"/> Guamanian or Chamorro ²⁰⁹¹ <input type="checkbox"/> Samoan ²⁰⁹² <input type="checkbox"/> Other Island ²⁰⁹³	
Hispanic or Latino Ethnicity ²⁰⁷⁶ : <input type="radio"/> No <input type="radio"/> Yes	→ If Yes, Ethnicity Type: (check all that apply)	
	<input type="checkbox"/> Mexican, Mexican-American, Chicano ²¹⁰⁰ <input type="checkbox"/> Puerto Rican ²¹⁰¹ <input type="checkbox"/> Cuban ²¹⁰² <input type="checkbox"/> Other Hispanic, Latino or Spanish Origin ²¹⁰³	
B. EPISODE OF CARE		
Arrival Date/Time ³⁰⁰¹ : mm / dd / yyyy / hh:mm		
Admitting Provider's Name, NPI ^{3050,3051,3052,3053} :	Last Name, First Name, MI, NPI	
Attending Provider's Name, NPI ^{3055,3056,3057,3058} :	Last Name, First Name, MI, NPI	
Health Insurance ³⁰⁰⁵ : <input type="radio"/> No <input type="radio"/> Yes		
→ If Yes, Payment Source ³⁰¹⁰ : (Select all that apply)	<input type="checkbox"/> Private Health Insurance <input type="checkbox"/> Medicare (Fee-For-Service) <input type="checkbox"/> Medicare Advantage <input type="checkbox"/> Medicaid <input type="checkbox"/> Military Health Care <input type="checkbox"/> State-Specific Plan (non-Medicaid) <input type="checkbox"/> Indian Health Service <input type="checkbox"/> Non-US Insurance	
MBI # ¹²⁸⁴⁶ :		
Residence ¹³⁸⁰³ : <input type="radio"/> Home with No Health Aid <input type="radio"/> Home with Health Aid <input type="radio"/> Long Term Care <input type="radio"/> Other <input type="checkbox"/> Not Documented ¹³⁸⁰⁴		
RESEARCH STUDY		
Patient Enrolled in Research Study ^{3020 (A)} : <input type="radio"/> No <input type="radio"/> Yes	<input type="checkbox"/> Patient Restriction ³⁰³⁵	
→ If Yes, Research Study Name ³⁰²⁵ , Research Study Patient ID ³⁰³⁰ :		
TRANSCATHETER VALVE THERAPY (TVT) PATHWAY		
TVT Pathway ^{13171 (A)} : <input type="checkbox"/> TAVR <input type="checkbox"/> TMVr <input type="checkbox"/> TMVR <input type="checkbox"/> Tricuspid Valve Procedure		
C. HISTORY AND RISK FACTORS		
Height ⁶⁰⁰⁰ : _____ cm	Weight ⁶⁰⁰⁵ : _____ kg	
Number of Prior Open Heart Cardiac Surgeries ¹³⁶⁹⁷ : _____	(If the patient has had >4 prior surgeries and the number is not known, code 4 prior surgeries)	
Heart Failure Hospitalization Within Past Year ¹³⁷⁰⁷ : <input type="radio"/> No <input type="radio"/> Yes <input type="checkbox"/> Not Documented ¹⁴²⁵³		
Anticipated Life Expectancy of Less than 1 Year ^{13172 (A)} : <input type="radio"/> No <input type="radio"/> Yes <input type="checkbox"/> Not Documented ¹⁴⁴⁵⁴		
Oxygen at Home ¹³⁸⁸¹ : <input type="radio"/> No <input type="radio"/> Yes		
Immunocompromise Present ¹³⁸⁸² : <input type="radio"/> No <input type="radio"/> Yes	Currently on Dialysis ¹³⁸⁸⁰ : <input type="radio"/> No <input type="radio"/> Yes	
Tobacco Use ⁴⁶²⁵ : <input type="radio"/> Never <input type="radio"/> Former <input type="radio"/> Current-Every Day <input type="radio"/> Current-Some Days <input type="radio"/> Smoker – Current Status Unk <input type="radio"/> Unk if ever smoked		
→ If any Current, Tobacco Type ⁴⁶²⁶ (Select all that apply): <input type="checkbox"/> Cigarettes <input type="checkbox"/> Cigars <input type="checkbox"/> Pipe <input type="checkbox"/> Smokeless		
→ If Current Every Day and Cigarettes, Amount ⁴⁶²⁷ : <input type="radio"/> Light tobacco use (<10/day) <input type="radio"/> Heavy tobacco use (≥10/day)		

Basic dataset (BDS)

(A)= Data element used for "appropriate use criteria (AUC)" metrics

Appropriate Use Criteria (AUC)

1. History: Anticipated life expectancy <1 year (13172)
2. Condition history (12903): Dementia (mod-sev)
3. Pre-procedure
 - a. Presentation and Eval: Sx of AS present (13186)
 - b. Cath: Syntax score (13496)
 - c. CTA: AV Calcification Severity (13423)
 - d. Echo:
 - i. Ascending aorta size (13469)
 - ii. Low flow (13700)
 - iii. MV Disease Etiology (13739)
 - e. If Low flow – Dobutamine Challenge
 - i. Dobutamine Challenge (13319)
 - ii. Flow Reserve Present (13320)
 - iii. AS Stenosis Type (13321)

TVT Registry Public Reporting – optional



**The Society
of Thoracic
Surgeons**

**STS/ACC TVT Registry
Public Reporting Metrics
Patients with TAVR as of 2019 q4
Hospital ABC (123456)**



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Timeframe First TAVR Procedure Performed	My Hospital TAVR Volume (commercial procedures only)		Distribution of Annual Hospital Volume
	Cumulative	Average annual volume (Jan 1 2017 to Dec 31, 2019)	
December, 2011	750	60	

My Hospital TAVR 30 Day Composite ^{1,2} (95% Interval)	Eligible Patients (Jan 1, 2017 –Dec 31, 2019)	Participant Rating	Distribution of Participant Estimates
0.05 (-0.15 to 0.12)	160	★★★	

¹ 30 Day Composite consists of six ordered categories based on the worst possible outcome (30-day death) to the best possible outcome (e.g. alive and free of major complications) during hospitalization and the 30-day follow-up period as defined below:

1. 30-day death
2. 30-day stroke
3. 30-day life-threatening/major bleed
4. Acute kidney injury (stage III)
5. 30-day $\geq 2+$ (mod-sev) paravalvular leak
6. None of the above

²The TAVR 30-day Mortality/morbidity composite is reported as a “win difference”

>0 implies “My Hospital” has better than expected performance

<0 implies “My Hospital” has worse than expected performance

Outreach

- Correspondence with TAVR hospitals
 - Previous webinars (on HCAI website)
 - Bi-monthly conference calls with CABG hospitals in 2022 – included TAVR updates
 - Bi-monthly conference calls in 2023 will include both TAVR and CABG updates (first one January 5, 2023, 2 pm)
 - Additional webinars if needed
 - TAVR mailbox TAVR@hcai.ca.gov
- Regulations 45-day public comment period – no comments received
- Ongoing communications with CA ACC and California Society of Thoracic Surgeons.
- Public CAP meetings

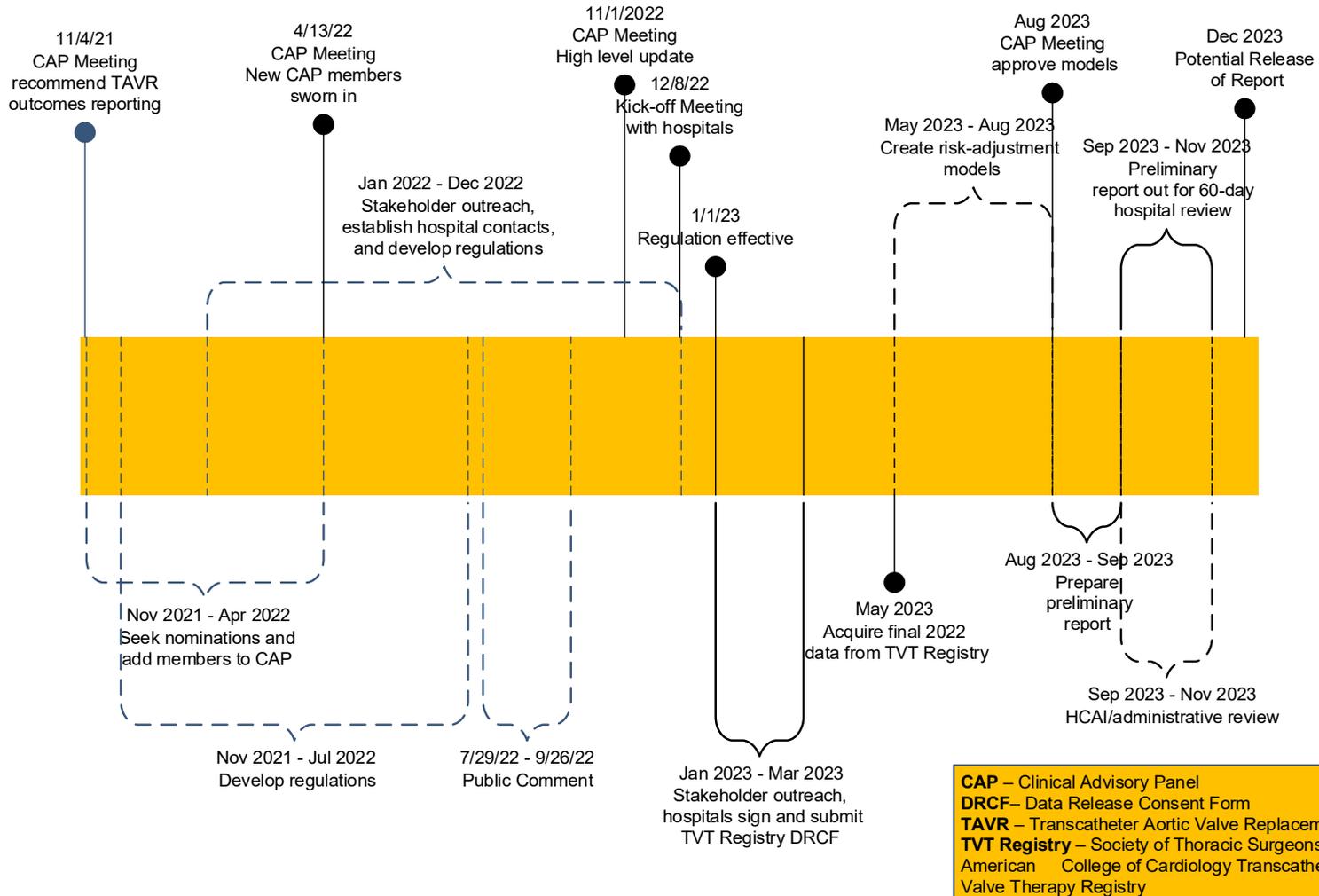
Next Steps for TAVR Hospitals

- Prior to January 1, 2023
 - Review regulations
 - Review Data Release Consent Form (DRCF)
 - Determine and reach out to staff who will sign the DRCF
 - Hospital participant
 - Surgeon participant
 - Cardiologist participant
 - Submit any questions to TAVR@hcai.ca.gov

Next Steps for TAVR Hospitals

- After January 1, 2023
 - Obtain Cardiac Online Reporting for California (CORC) access
 - (more information will be shared in January)
 - Enter data contact information in CORC by January 30, 2023
 - DRCF
 - Obtain signatures
 - Scan and email the completed form to:
 - ncdrmail@acc.org by March 1, 2023
 - Upload copy of finalized DRCF in CORC or email to TAVR@hcai.ca.gov
 - Submit timely TAVR data to the TVT Registry
 - Participate in bi-monthly conference calls with HCAI
 - Participate in public CAP meetings if interested. CAP will discuss:
 - Risk factors for adjustment
 - Outcomes
 - Public report format
 - Hospital-specific reports
 - Audits
- Submit any questions to TAVR@hcai.ca.gov

Projected Timeline for Initial Hospital Public Report on TAVR (2022 Data)



New Q and As

Thank you!

Feel free to contact us at:

TAVR@hcai.ca.gov